SEP 2 6 2000

K000095

510(k) SUMMARY
Olympus SonoSurg Trocar XT3900 System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Section 807.92.

A. Submitter's Name, Address Phone and Fax numbers

1. Manufacturer of the subject device

Name & Address of Manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjuku Monolis Nishi-shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration No:	8010047
Address, Phone and Fax numbers of R&D department Endoscope division	12951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan Telephone: 81.426.42.5101 Facsimile: 81.426.46.2786

2. **Name of Contact Person**

Name:	Laura Storms-Tyler Olympus America Inc.
Address, phone and fax:	Two Corporate Center Drive Melville, NY 11747-3157 Telephone: 516.844.5688 Facsimile: 516.844.5416

B. Device Name, Common name

1. Device Name:	Olympus SonoSurg Trocar XT3900 System
2. Common/Usual Name:	Ultrasonic Surgical System
3. Classification Name:	No classification

C. Predicate Devices:

#K924281	Harmonic Scalpel Laparoscopic Blade System
#K930215	Flexible Trocar Tubes
#K952726	Harmonic Scalpel LCS
#K9629652	Olympus Ultrasonic Surgical System
#K972114	Olympus SonoSurg System SonoSurg-G

D. Summary Description of the Device

1. Summary

The Olympus SonoSurg Trocar XT3900 System is an Ultrasonic trocar for endoscopic surgery which enables the puncture and cutting of the abdominal wall with tissue coagulation by means of ultrasonic vibration. Olympus SonoSurg Trocar XT3900 System is composed of two sections, the Olympus SonoSurg Trocar XT3900 and the Olympus SonoSurg Generator SonoSurg-G2.

The Olympus SonoSurg Trocar XT3900 is composed for a trocar transducer, probe, main unit, sleeve, thread, and Olympus SonoSurg Generator SonoSurg-G2, which provides ultrasonic vibration to the Olympus SonoSurg Trocar XT3900.

2. Design

The Olympus SonoSurg Generator SonoSurg-G2 has been designed, manufactured and tested in compliance with Voluntary Safety Standards. It meets the requirements of IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2.

3. Materials

There are no new patient contacting materials.

E. Intended Use of the Device

This instrument has been designed to be used with an Olympus SonoSurg Generator SonoSurg-G2 to cut and coagulate tissues for endoscopic surgery.

F. Technological Characteristics

Theory of the operation of Olympus SonoSurg Trocar XT3900 is that the electrical energy employed in the generator is changed to mechanical energy by ultrasonic vibration in the handpiece. System can cut and coagulate body tissue by ultrasonic vibration. This system is equivalent the predicate device, the Olympus SonoSurg System SonoSurg-G (K972114).

G. Reason for not requiring clinical data

When compared to the predicate device, the Olympus SonoSurg Trocar XT3900 does not incorporate any significant change that impacts safety and efficacy in comparison to the predicate device. Therefore, clinical data is not necessary to establish the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2000

The Olympus Optical Company
c/o Ms. Laura Storms-Tyler
Olympus America, Inc.
Two Corporate Center Drive
Melville, New York 11747

Re: K000095
Trade Name: Olympus SonoSurg Trocar XT3900 System
Regulatory Class: II
Product Code: LFL
Dated: June 22, 2000
Received: June 28, 2000

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number(if known): Not assigned yet K000095

Device Name: Olympus SonoSurg Trocar X3900 System

Indications for Use:

This instrument has been designed to be use with an Olympus SonoSurg GENERATOR SonoSurg-G2 to cut and coagulate tissues for endoscopic surgery.

Mark N. Milleson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000095

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optoinal Format 1-2-96)